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### REMARKS

Claims 23 and 49 are cancelled. Claims 1, 24, and 31 are amended herein. Claims 1-22, 24-48, 50-53 are currently pending. No new matter has been added by the amendment.

1. Claims 1, 2, 6, 13, 16, 18, 19, 20-24, 27, 31, 34, 40, 43, 45-51 and 53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,338,295 (Cornelius et al.) in view of U.S. Patent No. 5,674,276 (Andersen et al.). In supporting the rejection, the Examiner suggested:

Cornelius et al. discloses a catheter (10) comprising an elongate tubular member (12) having a proximal end, distal end, and a passageway defining a lumen (28) extending between the proximal and distal ends, said elongate tubular member comprising a braid (52) and an inner tubular liner (24) in coaxial relationship with the knit tubular member. Cornelius et al. discloses the braid which is woven in a "clothing weave" (column 2, lines 29-32). Webster's Ninth New Collegiate Dictionary defines weave: to form (cloth) by interlacing strands. Webster's defines knit: to form by interlacing yarn or thread in a series of connected loops with needles. Therefore a weaved braid is the same as a knit. Cornelius et al. further discloses an outer cover (22); a braid tubular member formed from metal wire (col 2, lines 29-30); a relatively stiff proximal segment and relatively flexible distal segment (col 3, lines 51-53); a knit tubular member comprised a metal alloy/stainless steel (col 2, line 29) having a generally circular cross-sectional shape (column 2, line 31); wherein at least one of the inner tubular liner and the outer tubular cover are radiopaque (36); a knit tubular member that is generally not radially expandable; an inner proximal liner (24) and an outer proximal cover (26); a braid interposed between the inner proximal liner and the outer proximal cover (fig. 2); a knit tubular member extending into the proximal segment (fig. 2).

Cornelius does not disclose a knit tubular member being formed from a plurality of interlocking loops. Andersen et al. does teach a knit tubular member being formed from a plurality of interlocking loops (fig 1a). It would have been obvious to one of ordinary skill in the art to modify the invention of Cornelius to include the knit formed from a plurality of interlocking loops as taught by Andersen et al. so that the knit has more structural integrity, therefore having a stronger wall but allowing flexibility.

Applicants respectfully disagree with the rejection for the following reasons.

A. Nonanalogous art is the antithesis of prima facie obviousness.

It is a settled legal principle that Section 103 nonobviousness requirement does not presume full knowledge of the inventor of prior art outside the field of his endeavor, i.e., of “nonanalogous” art. In re Winslow, 151 USPQ 48 (CCPA 1966).

The Cornelius device is a catheter used to access remote regions of the human body and, in doing so, delivering diagnostic or therapeutic agents to those sites. The Andersen device is a stent. It remains in the body to perform various functions, such maintain an opening of an esophagus or a blood vessel. They are two kinds of medical devices performing drastically different functions, and one cannot be substituted by the other. A person of ordinary skill in the art would not have looked to a stent to solve the problems treated by a catheter. Therefore, a prima facie case of obviousness has not been established in the first place.

B. The structures and utilities of the knit interlocking loops are different.

A knit tubular member of the present invention that is formed from a plurality of tightly knit interlocking loops and not radially expandable is absent in the Cornelius catheter. The interlocking loops in the Andersen prosthesis are loosely knit (column 4, lines 26 and 58). Such structure in Andersen is provided for the purposes of (a) allowing

the wall portion of the prosthesis to be expandable to a desired size by means of an internal expanding force (column 3, lines 18-19), (b) providing substantial open area to facilitate wrapping the prosthesis into small size for delivery intralumenally (column 4, lines 57-61), and (c) letting the loops be free to slide with respect to each other while in use in the body, therefore, enhancing the ability of the device to maintain its axial working length and resist migration when the prosthesis is locally radially compressed (column 5, lines 15-18).

On the contrary, claim 1 of the present Application as currently amended requires the interlocking loops to be tightly knit and the knit member to be not radially expandable (e.g., does not increase in diameter more than about 5% when an outwardly directed radial force is applied to an inner surface of the knit member) (see page 8, lines 16-20 of the Specification). The main function of the knit tubular member in the present invention is kink resistance (see page 3, lines 18-19 of the Specifications). Therefore, it is clear that the structures of the interlocking loops as well as the purposes for using them in the present invention are substantially different from those in the Andersen prosthesis. It should not have been obvious to one with ordinary skill in the art to modify the interlocking loops of the Anderson prosthesis and incorporate them into the Cornelius catheter body.

C. References are not properly combinable or modifiable if their intended function is destroyed.

A 35 U.S.C. §103 rejection based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in the reference is not proper and the prima facie case of obviousness cannot be properly made. In short, there would be no technological motivation for engaging in the modification or change. To the contrary, there would be a disincentive. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

As discussed above, if the interlocking loops in Andersen are modified to be tightly knit and not radially expandable as required by the amended claim 1 of the present Application, they will inhibit, rather than allowing the wall portion of the prosthesis to be

expandable. Neither will they be free to slide with respect to each other while in use in the body, therefore, decreasing, rather than enhancing, the ability of the prosthesis to maintain its axial working length and resist migration when the prosthesis is locally radially compressed. Again, a prima facie case of obviousness has not been made.

D. The invention, including its advantages, should be viewed as a whole under 35 U.S.C. §103 review.

In asserting the differences between the prior art and the claims at issue under 35 U.S.C. §103, it is essential to view the claims at issue as “the invention as a whole.” In so doing, it is legally improper to focus on the obviousness of substitutions and differences between the claimed invention and the prior art rather than on the obviousness of the claimed invention as a whole relative to the prior art. Hybritech, Inc. v Monoclonal Antibodies, Inc., 802 F.2d 1367, 1383, 231 USPQ 81, 93 (Fed. Cir. 1986), cert. den., 480 US 947 (1987) (emphasis added). It is impermissible to ignore the advantages, properties, utilities, and unexpected results flowing from the claimed invention; they are part of the invention as a whole. In re Chupp, 816 F.2d 643, 2 USPQ2d 1437 (Fed. Cir. 1987); Fromson v. Advance Offset Plate, 755 F.2d 1549, 225 USPQ 26 (Fed. Cir. 1985); In re Piasecki, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984); Carl Schenck, A.G. v. Norton Corp., 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983); In re Sernaker, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983).

The present invention utilizes the concept of combining one or more polymeric tubes with a knit tube made of tightly knit interlocking loops. Such construction has the benefit of producing catheter sections that have small overall diameters but with exceptional strength, resistance to ovalization and kinking, and recovery from kinking (even in vivo) should such kinking occur. In addition, the catheter section of the present invention may be made in such a way that the wall is extraordinarily thin, particularly when compared to the walls of catheters having equal strength but made solely of polymeric materials.

Knit tubular members have been used in surgical devices, such as the one in Anderson. However, none of the references teaches a combination of polymeric tubing with a knit tubing made of tightly interlocked loops, resulting in improved flexibility and kink resistance. Therefore, the main advantages and unexpected results of the present invention are missing in the referenced prior art, but are part of the present invention that the Applicants respectfully request the Examiner to take into consideration.

E. There is no teaching, suggestion or incentive in the reference patents to combine their teachings.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. In re Geiger, 815 F.2d at 688, 2 USPQ2d at 1278 (Fed. Cir. 1987) (quoting ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir 1984)) (emphasis added).

Cornelius discloses a catheter comprising an elongated tubular member having a proximal end, distal end, and a passageway defining a lumen extending between the proximal and distal ends, said elongate tubular member comprising a braid and an inner tubular liner in coaxial relationship with the knit tubular member, which is woven in a "clothing weave." Cornelius does not disclose a knit tubular member being formed from a plurality of tightly knit interlocking loops.

On the other hand, Andersen et al. does teach a knit tubular member being formed from a plurality of interlocking loops. However, as discussed above, the interlocking loops in Andersen are loosely knit, for the purposes of (a) allowing the wall portion of the prosthesis to be expandable to desired size by means of an internal expanding force, (b)

providing substantial open area to facilitate wrapping the prosthesis into small size for delivery intralumenally, and (c) letting the loops be free to slide with respect to each other while in use in the body. The purpose of the tightly knit interlocking loops that are not radially expandable in the present invention is to improve the catheter's kink resistance and reduce the diameter of the catheter while providing the same strength as compared to a catheter made solely in polymeric material but with thicker walls. There is no teaching, suggestion or incentive found in Andersen that would lead a person with ordinary skill in the art to first tighten the interlocking loops in a prosthesis and then use them with a catheter in the same way as the present invention.

In light of the above discussion, the Applicants respectfully request the withdrawal of the rejection to claims 1, 24 and 31, as well as claims 2, 6, 13, 16, 18, 19, 20-22, 27, 34, 40, 43, 45-51 and 53 that depend directly or indirectly from them.

2. Claims 3-5, 7-9, 14-15, 17, 22, 25-26, 32-33, 35-37, 41-42, 44 and 52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,338,295 (Cornelius et al.) in view of U.S. Patent No. 5,674,276 (Andersen et al.), and further in view of U.S. Patent No. 5,702,373 (Samson et al.). In support of the rejection, the Examiner stated:

Cornelius discloses all of applicant claims with the exception of a the [sic] knit tubular member comprised of super elastic alloy, nickel-titanium alloy, nitinol, platinum alloy, non-metallic material, or polymeric material; wherein the wire has a diameter of about .3 mil - 1.5 mil.; comprises a first strand made from a first material and a second made from a second material; an outer tubular cover

comprised of a material selected from the group consisting of polyimide [sic], polyamide, polyethylene, polypropylene, polyvinyl chloride, including PTFE, FEP, Nylon, polyether block amide, vinylidene fluoride, and their mixtures, alloys, copolymers, and block copolymers; an inner tubular liner comprised of a material selected from the group consisting of polyethylene, fluoropolymer, Nylon, polyether block amide, polyvinyl chloride (PVC), ethyl vinyl acetate (EVA), polyethylene terephthalate (PET), and their mixtures, alloys, and copolymers, and a coil interposed between the inner proximal liner and the outer proximal cover. Samson discloses a knit tubular member comprising a super elastic alloy (column 7, line 64), nickel-titanium alloy (column 8, lines 10-12), nitinol (column 8, lines 10-12), platinum alloy (column 12, lines 6-7), non-metallic material (column 12, lines 10-12), polymeric material (column 12, line 10-12); wherein the wire has a diameter of about .3 mil - 1.5 mil (column 11, lines 60-62); comprises a first strand made from a first material and a second made from a second material (column 11, lines 28-32); an outer tubular cover comprised of polyethylene (column 10, line 36), polyvinyl chloride (column 10, line 49); and an inner tubular liner comprised of polyethylene (column 10, line 27), PVC (column 10, line 27), EVA (column 10, line 28), PET (column 10, line 28); and a coil (282) interposed between the inner proximal liner and the outer proximal cover. It would have been obvious to one having ordinary skill in the art to modify the catheter of Cornelius et al. in view of Andersen et al. to use the above mentioned materials and diameter of wire as taught by Samson to help prevent kinking of the catheter tube.

Applicants respectfully disagree. Samson discloses a composite super-elastic alloy braid reinforced catheter having a braided ribbon (Figures 2-12). It does not show or suggest a knit member having a plurality of tightly knit interlocking loops that are not radially expandable as set forth in the present claims. As discussed above, the primary reference does not teach the invention as claimed and the secondary references fail to remedy the basic lacking of the primary reference. Reversal of the rejections is therefore



requested.

3. Claims 10-12, 28-30, 38-39 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,338,295 (Cornelius et al.) in view of U.S. Patent No. 5,674,276 (Andersen et al.), and further in view of U.S. Patent No. 5,702,373 (Samson et al.) as applied to claims 3-5, 7-9, 14-15, 17, 22, 25-27, 32-37, 41-42, 44, and further in view of U.S. Patent No. 5,549,109 (Samson et al). In support of the rejection, the Examiner stated:

Cornelius et al. in view of Samson teach all the elements of applicant's claims with the exception of a knit tubular member comprised of a multi filament wire. Samson et al. discloses multi filament tubes (302) that are woven (column 9, 65-67). It would have been obvious to one having ordinary skill in the art to modify the catheter of Cornelius et al. in view of Andersen et al., and further in view of Samson to use a multi filament wire as taught by Samson et. al to improve kinking resistance. Samson discloses the use of stainless steel, platinum and nitinol as the material for the wire. Therefore it would have also been obvious to use stainless steel and platinum or material selected from the group consisting of stainless steel, platinum, and nitinol as the material for the multi filament wire to improve kinking resistance.

First of all, since claims 1, 24 and 31 as amended are submitted as patentable for the reasons stated above, and claims 10-12, 28-30 and 38-39 depend directly or indirectly upon claims 1, 24 and 31 respectively, rejection to these claims should be withdrawn as well.

Furthermore, Samson ('373) discloses a composite super-elastic alloy braid reinforced catheter having a braided ribbon (FIGS. 2-12). Samson ('109) discloses a catheter having a woven section (FIG. 4). Neither of the Samson references discloses,

teaches or suggests a knit tubular member formed from a plurality of tightly knit interlocking loops. Neither of these secondary references remedies the fundamental deficiencies of the primary references as listed above. Applicants find it difficult to understand how the filament wire made of stainless steel, platinum or nitinol and used in a woven braid of a catheter would have rendered it obvious to one having ordinary skill in the art to use the same filament wire to form interlocking loops for another catheter, if such person of ordinary skill in the art has not come up with the idea of tightly knit interlocking loops for a catheter in the very beginning.


In view of the foregoing, claims 1-22, 24-48 and 50-53 are submitted as patentable over Cornelius et al., Andersen et al. and Samson et al. and the prior art of record. Accordingly, favorable reconsideration and allowance of this patent application is requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no.

290252021800. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: November 5, 1999 By:

  
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**2 a** : a sudden  
**brain-storm** *n*  
nique that i  
members of :  
**brains trust** *n*  
**brain-teaser** *n*  
mental effort  
**brain trust** *n*  
cerned esp. v  
**brain-wash** *vb*  
(1950) **1** : a  
political, soc  
trasting regir  
ship — **brain**  
**brain wave** *n*  
of voltage be  
current **b** : :  
**brainy** \ˈbrā-i  
developed in  
**1 braise** \ˈbrāz  
OF *breze*, pro  
slowly in fat :  
**2 braise** *n* (ca.  
**1 brake** \ˈbrāk  
**2 brake** *n* [ME  
: the commo  
**3 brake** *n* [ME,  
instrument o  
breaking up t  
ing, and form  
**4 brake** *n* [ME  
with one kinc  
**5 brake** *n* [per  
ing or preven  
**2** : something  
terest rates as  
**6 brake** *vb* **bral**  
**1** : to operate  
**2** : to become  
**brake-man** \ˈt  
member who  
man on a bob  
**bram-ble** \ˈbrā  
broom] (bef.  
rose family i  
rough prickly  
**bran** \ˈbrān\ *n*  
al grain separ  
**1 branch** \ˈbrai  
paw] (14c) **1**  
shoot or stem  
: something th  
**a** (1) : a strear  
(2) *Southern* &  
projection (as  
matical curve  
a program dec  
family descen  
edge that may  
~ of medicin  
but dependent  
inclusive than  
guage family)  
ləs\ *adj* — **br**

**bräun-schweig-er** \ 'bräun-,shwi-gər.  
schweiger (Wurst), lit., Brunswick sausage  
-va \ 'brä-(,)vā, brä-'vā\ *n* [lt, fem  
perfective]

or shape by or as if  
**ad-er** *n*

**OHG** *kneo* knee, *L*  
: part of the human  
a, and patella; also  
the joint in the hind  
o the human knee  
vertebrate *c* : the  
r and tibia of an in-  
a : a piece of tim-  
ng structures com-  
b : a rounded or  
amp-growing trees  
e knee 4 : a blow  
**knees** : into a state

end the knee to 2

act or practice of  
**up** *vt*

s (<~ in mud) **b**

**E-HIGH**

d to the knees (<~

er a desk) for the

stable : AUTOMAT-  
ble way (<~ liber-

duced by a light

**ME** *knelen*, fr. *OE*  
d the knee : fall or

ething (as a cush-

any joke, line, or

*knellen* to toll] *vt*  
*knell* ~ *vi* 1 : to  
sound in an om-

when rung slowly  
of the end or the  
opes)

*ckerbocker*, ficti-  
on Irving] (1848)  
York; broadly : a  
- used as a nick-

(1881) 1 : loose-  
: UNDERPANTS  
small trivial arti-

fr. *OE* *cnif*, perh.  
a cutting instru-

**Knights of the Macca-bees** \-'ma-kə-bēz\ *n*, *pl* **Knights of the**  
**cabees** (1922) : a member of a secret benevolent society

**Knight Templar** *n*, *pl* **Knights Templars** or **Knights Templar**

1 : **TEMPLAR** 2 : a member of an order of Freemasonry, con-

three orders in the York rite

**knish** \kə-'nish\ *n* [*Yiddish*, fr. *Pol* *knysz*] (1916) : a small ro-

square of dough stuffed with a filling (as potato) and baked or fr-

**knit** \nit\ *vb* **knit** or **knit-ted**; **knit-ting** [*ME* *knitten*, fr. *OE* *cnotta* knot] *vt* (bef. 12c) 1 chiefly *dial* : to tie together

: to link firmly or closely (<*knitted* my hands) **b** : to cause to cre-

gether <time and rest will ~ a fractured bone> **c** : to contract

wrinkles (<*knitted* her brow) 3 : to form by interlacing yarn or

in a series of connected loops with needles ~ *vi* 1 : to make

fabrics or objects 2 **a** : to become compact **b** : to grow together

: to become drawn together — **knit-ter** *n*

**knit** *n* (1596) : **KNIT STITCH**; also : a knit fabric

**knit stitch** *n* (ca. 1885) : a basic knitting stitch usu. made with the

at the back of the work by inserting the right needle into the front

of a loop on the left needle from the left side, catching the yarn

the point of the right needle, and bringing it through the first loop

form a new loop — compare **PURL STITCH**

**knit-ting** *n* (15c) 1 : the action or method of one that knits 2 : the

done or being done by one that knits

**knit-wear** \nit-,war-, -wer\ *n* (1926) : knitted clothing

**knob** \nəb\ *n* [*ME* *knobbe*; akin to *MLG* *knubbe* knob] (bef. 12c)

: a rounded protuberance : **LUMP** **b** : a small rounded ornament

handle 2 : a rounded usu. isolated hill or mountain — **knob-**

\nəbd\ *adj* — **knob-by** \nə-bē\ *adj*

**knob-bly** \nə-b(ə-)lē\ *adj* (1859) : having very small knobs (<*a* dress)

**knob-ker-rie** \nəb-,ker-ē\ *n* [*Afrikan* *knopkierie*, fr. *knop* knob

club] (1844) : a short wooden club with a knob at one end usu.

missile or in close attack esp. by Zulus of southern Africa

**knock** \näk\ *vb* [*ME* *knoken*, fr. *OE* *cnocian*; akin to *MHG* *knoc* press] *vi* (bef. 12c) 1 : to strike something with a sharp blow

collide with something 3 **a** : **BUSTLE** (<heard them ~ing around

kitchen> **b** : **WANDER** (<~ed about Europe all summer> 4 **a** : to

a pounding noise **b** : to have engine knock 5 : to find fault

(1) : to strike sharply (2) : to drive, force, or make by or as if

striking **b** : to set forcibly in motion with a blow 2 : to cause

slide 3 : to find fault with (<always ~ing those in authority> —

**cold** : **KNOCK OUT** 2a(1) — **knock dead** : to move strongly esp.

miration or applause (<a comedian who really *knocks* them off>

**knock for a loop** 1 **a** : **OVERCOME** (<*knocked* my opponent for

**b** : **DEMOLISH** (<*knocked* our idea for a loop> 2 : **DUMBFOUND**

<the news *knocked* them for a loop> — **knock one's socks**

overwhelm or amaze one (<a performance that will *knock* you

off> — **knock together** : to make or assemble esp. hurriedly

makeshift way (<*knocked together* my own bookcase>

**knock** *n* (14c) 1 **a** : a sharp blow : **RAP**, **HIT** (<a loud ~ on the door>

(1) : a severe misfortune or hardship (2) : **SETBACK**, **REVERSAL**

: a pounding noise **b** : a sharp repetitive metallic noise caused

